(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 June 2006 (08.06.2006)

PCT

(10) International Publication Number
WO 2006/060594 A1

(51) International Patent Classification:
A61B 17/068 (2006.01) *A61B 17/064* (2006.01)

(21) International Application Number:
PCT/US2005/043503

(22) International Filing Date:
30 November 2005 (30.11.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/004,445 3 December 2004 (03.12.2004) US

(71) Applicant *(for all designated States except US)*: **ARBOR SURGICAL TECHNOLOGIES, INC.** [US/US]; 22 Morgan, Irvine, CA 92614 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ING, Takashi, Harry** [US/US]; 848 Foothill Court, San Jose, CA 95123 (US). **DREWS, Michael, J.** [US/US]; 4524 O Street, Sacramento, CA 95817 (US). **GURSKIS, Donnell, W.** [US/US]; 924 Holly Road, Belmont, CA 94002 (US).

(74) Agent: **ENGLISH, William, A.**; Cohen & Sakaguchi & English LLP, 2040 Main Street, 9th Floor, Irvine, CA 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

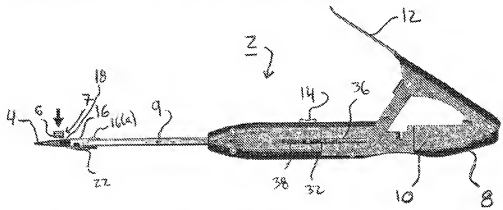
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHOD FOR DELIVERING FASTENERS DURING VALVE REPLACEMENT



(57) Abstract: A fastener delivery tool (2) includes a loading chamber for receiving a fastener (6) having a pair of tines (6a, 6b) overlapping one another to define a loop (6c) in a parent or relaxed state. A retaining member (20) retains the fastener in the loading chamber (7). The fastener delivery tool also includes a tongue (26), pusher member (30), and an ejection track (23) communicating with the loading chamber. An actuator (12) causes the tongue (26) to move to engage the tines (6a, 6b) of the fastener (6) to transform the fastener (6) from the relaxed state to a constrained state defining a U-shape. The actuator (12) also causes the pusher member (20) to release the retaining member and advance the fastener down the ejection track in the constrained state. The tool (2) also includes a trigger for ejecting the fastener completely from the ejection track. The fastener may be used to secure a prosthetic heart valve or components thereof into surrounding tissue, e.g., within a tissue annulus.

WO 2006/060594 A1

APPARATUS AND METHOD FOR DELIVERING FASTENERS DURING VALVE REPLACEMENT

FIELD OF THE INVENTION

tissue or other devices, and, more particularly, to apparatus and methods for delivering fasteners during heart valve replacement, placement of other prostheses, or repair of body organs in general and vascular surgery, such as wound closure, anastomosis, hernia repair, and grafting procedures for aneurysm repair.

BACKGROUND

Prosthetic heart valves have been used to replace defective human valves in patients. A prosthetic valve generally includes a sewing ring or suture cuff that may be attached to and/or extend around a valve member. The sewing ring may be made from a biocompatible fabric and/or other material through which a needle and suture may pass. The sewing ring may be part of a single piece prosthetic valve, or may be part of a multiple piece prosthetic valve assembly.

In a typical aortic valve replacement procedure, the aorta may be incised and the defective valve leaflets removed, leaving a desired placement site that may include a fibrous tissue layer or tissue annulus. Needles carrying sutures may be directed through the fibrous tissue or desired placement site within the tissue annulus to form an array of sutures. Free ends of the sutures may be extended out of the thoracic cavity and laid, spaced apart, on the patient's body.

The needles and sutures may then be threaded individually through a sewing ring, typically delivering between ten and twenty (12-20) sutures through the sewing ring.

Once the sutures have been directed through the sewing ring, the sutures may be pulled up taught and the sewing ring may be slid over the sutures or "parachuted" down into place adjacent the placement site tissue. The sewing ring may then be secured in place by knot tying knots in the sutures. This procedure is time consuming as doctors often use three to ten knots per suture.

If the sewing ring is separate from a valve member of a multiple component prosthesis, the valve member may be introduced into the placement site, and secured to the sewing ring. The sutures may be tied, not only to secure the sewing ring to the biological mass and, but to secure the valve member to the sewing ring (and consequently, to the tissue annulus).

During heart valve replacement procedures, the patient may be on cardiopulmonary bypass (CPB), which may reduce the patient's oxygen level and/or create non-physiological blood flow dynamics. The longer a patient is on CPB, the greater the risk for long-term or even permanent health damage. Existing suturing techniques extend the duration of CPB and, consequently, increase the health risks due to the patient. Furthermore, the fixturing force created by suturing varies significantly from suture to suture, even for the same medical professional.

Sewing rings can also be tedious and time consuming to secure to a valve orifice. To assemble multiple component heart valves, for example, one component has to be sewn into another *in vivo*, resulting in a complex and time consuming process. The complexity of the procedure also provides a greater opportunity for mistakes and requires a patient to be on cardiopulmonary bypass for a lengthy period.

SUMMARY OF THE INVENTION

The invention is directed to apparatus and methods for fastening devices to tissue or other devices, and, more particularly, to apparatus and methods for delivering fasteners during heart valve replacement. The invention may be deployed to secure a prosthesis to surrounding tissue, or to secure one prosthesis to another, or a portion of a prosthesis to a coordinating prosthesis.

In accordance with one embodiment, a fastener delivery tool is provided that includes a loading chamber for receiving a fastener having a plurality of tines in a relaxed state. The tool also includes a releasable retaining member for limiting movement of the fastener within the loading chamber. An ejection track is coupled to the loading chamber. A handle is provided that includes a lever, and a tongue and pusher member coupled to the lever. Movement of the lever advances the tongue to engage the tines so as to transform the fastener from the relaxed state to a constrained state. Movement of the lever also advances the fastener from the loading chamber down the ejection track. A trigger is depressed to eject the fastener from the tool.

In another embodiment, a method for delivering a fastener is provided that includes providing a fastener delivery tool having a fastener therein, the fastener including a pair of tines in a relaxed state. The fastener is secured in the fastener delivery tool using a releasable retaining member. A tongue is advanced in the fastener delivery tool so as to transform the fastener from a relaxed state to a constrained state while the fastener is secured with the releasable retaining member. The retaining member is released and the fastener is advanced in the constrained state distally within the fastener delivery tool using a pusher member. The fastener is ejected from the fastener delivery tool by depressing an actuator.

In still another embodiment, a fastener delivery tool is provided that includes a loading chamber for receiving at least one fastener having a plurality of tines in a relaxed state, the loading chamber including a release pin on which said at least one fastener is loaded. The tool further includes an ejection track communicating with the loading chamber and a lever coupled to a tongue and a pusher member. The tongue is engageable with the plurality of tines of the fastener so as to transform the fastener from the relaxed state to a constrained state. The pusher member is also engageable with a proximal end (e.g., a loop portion) of the fastener so as to translate the fastener to a distal tip of the tool. The fastener is then ejected by depressing a trigger or other actuator.

In still another embodiment, a fastener delivery tool is provided that includes a staging area or section in which a plurality of fasteners are loaded. The fasteners may be loaded individually or within a cartridge. Multiple fasteners may be loaded into the tool, thereby permitting the user to eject or "fire" multiple fasteners successively without having to reload between ejections.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a fastener delivery tool including a cartridge containing a fastener being loaded into a loading chamber of the fastener delivery tool.

FIG. 2(a) is a cross-sectional side view of the distal tip of the fastener delivery tool shown in FIG. 1, showing the fastener being loaded into the loading chamber (arrow A).

FIG. 2(b) is a cross-sectional top view of the distal tip of the fastener delivery tool shown in FIG. 2(a).

FIG. 3(a) is a cross-sectional side view of the distal tip of the fastener delivery tool shown in FIG. 1, showing initial advancement of the cartridge retainer in the distal direction (arrow B).

FIG. 3(b) is a cross-sectional top view of the distal tip of the fastener delivery tool shown in FIG. 3(a).

FIG. 4(a) is a cross-sectional side view of the distal tip of the fastener delivery tool shown in FIG. 1, showing complete advancement of the cartridge retainer. As seen in FIG. 4(a), the tines of the fastener are closer together due to advancement of the cartridge retainer and coupled spreader.

FIG. 4(b) is a cross-sectional top view of the distal tip of the fastener delivery tool shown in FIG. 4(a), showing initial advancement of the tongue in the distal direction.

FIG. 5(a) is a cross-sectional side view of the distal tip of the fastener delivery tool shown in FIG. 1, showing a tongue advanced and entering a loop in the fastener.

FIG. 5(b) is a cross-sectional top view of the distal tip of the fastener delivery tool shown in FIG. 5(a), showing the tongue entering the loop in the fastener.

FIG. 6(a) is a cross-sectional side view of the distal tip of the fastener delivery tool shown in FIG. 1, showing transformation of the fastener into a constrained configuration (i.e., the U-configuration). Advancement of the tongue in the distal direction spreads the tines of the fasteners outward to form the U-configuration.

FIG. 6(b) is a cross-sectional top view of the distal tip of the fastener delivery tool shown in FIG. 6(a).

FIG. 7(a) is a cross-sectional side view of the distal tip of the fastener delivery tool shown in FIG. 1, showing translation of the fastener in the distal direction through advancement of a pusher member. The tongue is also translated in the distal direction along with the fastener to aid in maintaining the U-configuration.

FIG. 7(b) is a cross-sectional top view of the distal tip of the fastener delivery tool shown in FIG. 7(a), showing the tines of the fastener projecting slightly beyond the distal-most end of the fastener delivery tool.

FIG. 8(a) is a partial top down plan view of the fastener delivery tool of FIG. 1 with the handle and lever removed for clarity, and showing the loading chamber empty and ready for receiving a cartridge containing a fastener.

FIG. 8(b) is a cross-sectional side view of the fastener delivery tool of FIG. 8(a) taken along the line A-A.

FIG. 9(a) is a partial top down plan view of the fastener delivery tool of FIG. 1 with the handle and lever removed for clarity, and showing a fastener loaded in the loading chamber of the fastener delivery tool.

FIG. 9(b) is a cross-sectional side view of the fastener delivery tool of FIG. 9(a) taken along the line B-B.

FIG. 10(a) is a partial top down plan view of the fastener delivery tool of FIG. 1 with the handle and lever removed for clarity, and showing the cartridge retainer advanced distally to secure the fastener via a spreader that draws the two tines of the fastener closer to one another.

FIG. 10(b) is a cross-sectional side view of the fastener delivery tool of FIG. 10(a) taken along the line C-C.

FIG. 11(a) is a partial top down plan view of the fastener delivery tool of FIG. 1 with the handle and lever removed for clarity, and showing the tongue advanced distally to drop into a loop portion of the fastener.

FIG. 11(b) is a cross-sectional side view of the fastener delivery tool of FIG. 11(a) taken along the line D-D.

FIG. 12(a) is a partial top down plan view of the fastener delivery tool of FIG. 1 with the handle and lever removed for clarity, and showing additional distal displacement of the tongue to transform the fastener into the U-configuration.

FIG. 12(b) is a cross-sectional side view of the fastener delivery tool of FIG. 12(a) taken along the line E-E.

FIG. 13(a) is a partial top down plan view of the fastener delivery tool of FIG. 1 with the handle and lever removed for clarity, and showing the fastener advanced distally such that the two tines project slightly beyond the distal-most edge of the ejection track of the fastener delivery tool.

FIG. 13(b) is a cross-sectional side view of the fastener delivery tool of FIG. 13(a) taken along the line F-F.

FIG. 14(a) is a partial top down plan view of the fastener delivery tool of FIG. 1 with the handle and lever removed for clarity, and showing the ejection of the fastener from the ejection track of the fastener delivery tool in a U-shaped configuration.

FIG. 14(b) is a cross-sectional side view of the fastener delivery tool of FIG. 14(a) taken along the line G-G.

FIG. 15(a) is a side view of a fastener delivery tool according to one aspect of the invention, showing a cartridge being loaded into the loading chamber of the device.

FIG. 15(b) is a side view of a fastener delivery tool shown in FIG. 15(a), showing the cartridge retainer being advanced in the distal direction (see arrow in FIG. 15(b)) over the cartridge.

FIG. 15(c) is a side view of a fastener delivery tool shown in FIG. 15(a), showing the fastener being transferred from the cartridge to the distal tip of the fastener delivery tool by actuation of the lever.

FIG. 15(d) is a side view of a fastener delivery tool shown in FIG. 15(a), showing compression of the ejection spring by additional actuation of the lever.

FIG. 15(e) is a side view of a fastener delivery tool shown in FIG. 15(a), showing the fastener delivery tool being fully loaded and ready to deploy the fastener.

FIGS. 16(a) and 16(b) are top and side views of the distal end of a fastener delivery tool, illustrating exemplary configurations for an elongated distal tip for the tool.

FIG. 17(a) is a cross-section of a patient's body, showing a prosthetic valve secured within a tissue annulus by exemplary fasteners.

FIG. 17(b) is a cross-section of a patient's body, showing a fastener delivery tool delivering a fastener through a portion of a prosthetic valve into the surrounding tissue.

FIG. 17(c) is a radiograph showing a plurality of fasteners deployed about the circumference of a prosthetic valve.

FIG. 18 is an alternative embodiment of a fastener delivery tool that houses a plurality of fasteners.

DETAILED DESCRIPTION

Turning to the drawings, FIG. 1 shows a first embodiment of a fastener delivery tool 2. The fastener delivery tool 2 includes a distal tip 4 or snout from which one or more

fastener(s) 6 (described in more detail below) may be ejected and a proximal end 8 that may be grasped by a user during positioning and delivery of the fastener 6. The distal tip 4 and proximal end 8 of the tool 2 are separated by an elongated shaft 9. The fastener 6 may be stored within a cartridge 7 that may be loaded into the fastener delivery tool 2. The fastener delivery tool 2 also includes a proximally located handle 10 having a lever 12 or other actuator that may be used to deploy the fastener(s) 6. The handle 10 may be ergonomically shaped such that a user may easily manipulate the fastener delivery tool 2 into position. The handle 10 preferably includes a spring-biased trigger 14, e.g., a depressible button that may be used to eject the fastener 6 from the distal tip 4 of the tool 2.

A cartridge retainer 16 is provided on the shaft 9 that may be movable along the axial direction of the shaft 9. As described more fully below, the cartridge retainer 16 may be used to retain or otherwise secure the cartridge 7 for the subsequent deployment steps of the fastener 6. In addition, the cartridge retainer 16 may transform the fastener 6 into a partially constrained state.

FIGS. 2(a) and 2(b) illustrate the distal end of the fastener delivery tool 2. As best seen in FIG. 2(a), a fastener 6 may be pre-loaded in a cartridge 7, e.g., in a parent or relaxed state. In the relaxed state, the fastener 6 may include a pair of overlapping tines 6(a), 6(b) (best seen in FIG. 2(b)) that may be angled with respect to one another. The fastener 6 further includes a loop portion 6(c), e.g., defined by ends of the tines 6(a), 6(b). In an exemplary embodiment, the fastener 6 may be formed from an elastic or superelastic material, such as a Nickel-Titanium alloy (Nitinol). Additional information on exemplary embodiments of fasteners that may be delivered using the tool 2 are disclosed in co-

pending application Serial No. 10/681,700, filed October 8, 2003, the entire disclosure of which is expressly incorporated by reference herein.

The fastener 6 may be secured or otherwise retained in a groove 7(a) or slot in the cartridge 7. The cartridge 7 containing the fastener 6 may be inserted (in the direction of arrow A in FIG. 2(a)) into a loading chamber 18 located at the distal end of the shaft 9. During this loading process, the loop portion 6(c) of the fastener 6 may be lowered over a retaining member 20. The retaining member 20 may be movable between an engaged state (shown in FIG. 2(b)) and a disengaged state (described in more detail below). Preferably, the retaining member 20 is biased in the engaged state by a spring 22 or other biasing mechanism. The retaining member 20 advantageously secures the fastener 6 within the tool 2 during the process of transforming the fastener 6 from the relaxed, parent state to the constrained state (e.g., a U-shaped configuration).

Still referring to FIGS. 2(a) and 2(b), the distal tip 4 of the tool 2 includes an ejection track 23. The ejection track 23 is connected to or otherwise communicates with the loading chamber 18. During deployment of the fastener 6, the tines 6(a), 6(b) may be forced into the U-shaped configuration and the fastener 6 may be advanced from the loading chamber 18 and into the ejection track 23 (described in more detail below).

FIGS. 3(a) and 3(b) illustrate the next step involved in deploying the fastener 6. As seen in FIGS. 3(a) and 3(b), the cartridge retainer 16 may be advanced distally (shown by arrow B in FIG. 3(a)). In one embodiment, the cartridge retainer 16 may be advanced manually, for example, by depressing a finger on ridge 16(a). Alternatively, the cartridge retainer 16 may also be advanced automatically, for example, through movement of the handle 10. The cartridge retainer 16 is coupled to a spreader 24 that may engage the tines 6(a), 6(b) of the fastener 6. The spreader 24 may include a slot or groove in which the

fastener tines 6(a), 6(b) may be received. Movement of the cartridge retainer 16 from the position shown in FIGS. 3(a) and 3(b) to the position shown in FIGS. 4(a) and 4(b) causes the spreader 24 also to move distally. The spreader 24 contacts the tines 6(a), 6(b) of the fastener 6 and causes the fastener 6 to transform into a partially constrained state (best shown in FIG. 4(b)).

FIGS. 5(a) and 5(b) illustrate the tongue 26 advancing in the direction of arrow C shown in FIG. 5(b). As best seen in FIGS. 2(a) and 3(a), the tongue 26 includes one or more teeth 26(a). The tongue 26 is advanced in the direction of arrow C and the one ore more teeth 26(a) drop within the loop 6(c) of the fastener 6(c). FIGS. 5(a) and 5(b) illustrate the teeth 26(a) within the fastener loop 6(c). The tongue 26 is advanced further in the distal direction as shown in FIGS. 6(a) and 6(b) to transform the fastener 6 from the partially constrained state to the fully constrained state (i.e., the U-shaped configuration). The U-shaped configuration is obtained by forcibly parting the tines 6(a), 6(b) of the fastener 6 using the teeth 26(a) of the tongue 26, while restraining the proximal end or loop portion 6(c) of the fastener 6.

FIGS. 7(a) and 7(b) illustrate the fastener 6 being advanced through the ejection track 23. After the fastener 6 has assumed the U-shaped configuration, the retaining member 20 may be moved from the engaged state to the disengaged state. FIG. 7(a) illustrates the retaining member 20 in the disengaged state. With the retaining member 20 in the disengaged state, the fastener 6 may be free to move distally down the ejection track 23. In one embodiment, the retaining member 20 is moved from the engaged state to the disengaged state by interaction of a cam structure 20(a) located on the retaining member 20 with a pusher member 30 (see FIG. 7(a)). For example, in the engaged state, the cam structure 20(a) on the retaining member 20 may rest within a corresponding groove 30(a)

in the pusher member 30. When the pusher member 30 is advanced in the distal direction, the cam structure 20(a) is forced out of the groove 30(a) and forces the retaining member 20 to the disengaged state.

Still referring to FIGS. 7(a) and 7(b), the pusher member 30 contacts a proximal end of the fastener 6 and pushes or advances the fastener 6 down the ejection track 23. In one embodiment, the pusher member 30 continues to advance the fastener 6 until the fastener 6 reaches a position within the ejection track 23 shown in FIGS. 7(a) and 7(b). In this position, the faster 6 is positioned such that the tines 6(a), 6(b) project slightly from the distal-most end of the tool 2.

This configuration may permit a physician or other user to probe areas of tissue for the optimal insertion location. For example, the physician may probe an area of tissue that may be calcified or plaque-laden and not suitable for placement of a fastener 6. In this regard, the physician may move instead to another more potentially desirable location adjacent the calcified location. Once the desired location is reached, the fastener 6 may be completely ejected from the tool 2, e.g., by depressing the trigger 14 (shown, for example, in FIG. 15(e)).

FIGS. 8(a) and 8(b) illustrate partial top and side views, respectively, of the fastener delivery tool 2 with the handle 10 and lever 12 removed for clarity. In FIGS. 8(a) and 8(b), the loading chamber 18 of the device is empty and the cartridge retainer 16 is withdrawn in the proximal direction, permitting loading of another cartridge 7 carrying a fastener 6 into the tool 2. FIGS. 9(a) and 9(b) illustrate a fastener delivery tool 2 loaded with a single fastener 6 (the cartridge 7 is hidden simply for the sake of clarity). As seen in FIG. 9(a), the fastener 6 is in the relaxed or parent state. Referring now to FIGS. 10(a)

and 10(b), the cartridge retainer 16 is then advanced distally to partially constrain the fastener 6 within the spreader 24 (shown in FIG. 10(a)).

With reference to FIGS. 11 (a) and 11(b), additional depression of the lever 12 on the handle 10 advances the tongue 26 such that the teeth 26(a) drop into the loop portion 6(c) of the fastener (shown best in FIG. 11(b)). The tongue 26 is fixedly coupled to a trigger assembly 32 that may be translated distally as the lever 12 on the handle is depressed. The trigger assembly 32 is biased against an advancement mechanism 34 coupled to the actuating lever 12. Actuation of the lever 12 causes the advancement mechanism 34 to displace distally. This distal displacement is translated to the trigger assembly 32 via a spring 36. The spring 36 is preferably stiff such that it acts as a rigid linkage between the advancement mechanism 34 and trigger assembly 32 before the compression stage (discussed in detail below). Translation of the advancement mechanism 34 and trigger assembly 32 (and coupled tongue 26) before the compression stage may be best seen in FIGS. 11(a), 11(b), 12(a), and 12(b).

Referring now to FIGS. 12(a) and 12(b), the fastener 6 is then transformed into the fully constrained state (i.e., U-shaped configuration) by advancing the tongue 26 distally, e.g., by partially depressing the handle 10 of the tool 2. The teeth 26(a) of the tongue 26 may advance between the tines 6(a), 6(b) of the fastener 6 to direct the fastener 6 into the U-shaped configuration. At this stage, the fastener 6 may still be retained by retaining member 20.

FIGS. 13(a) and 13(b) illustrate the trigger assembly 32 abutting and pushing against a clamp 38 that is fixedly coupled to the pusher member 30. Movement of the clamp 38 distally causes corresponding distal movement of the pusher member 30 within the tool 2. The pusher member 30 then advances distally such that the cam 20(a) on the

retaining member 20 exits the groove 30(a) in the pusher member, thereby moving the retaining member 20 to the disengaged position. Additional advancement of the handle 12 pushes the fastener 6 down the ejection track 23 of the tool. During this phase of deployment, both the tongue 26 and pusher member 30 move distally in unison. Advancement of the fastener 6 may stop when the tines 6(a), 6(b) project just beyond the distal-most end of the tool 2 (as shown in FIGS. 13(a) and 13(b).

FIGS. 14(a) and 14(b) illustrate ejection of the fastener 6 from the tool 2. After the spring 36 has been fully compressed and the actuating lever 12 is in the position shown in FIG. 15(e), depression of the trigger 14 (illustrated by arrow D in FIG. 14(b)) causes the pusher member 30 to move rapidly in the distal direction to eject the fastener 6 completely from the ejection track 23. As best seen in FIG. 14(a), the fastener 6 may be ejected in the U-shaped configuration into the adjacent tissue (not shown).

As seen in FIGS. 8 through 14, the tool 2 may also include a proximally located restoring spring 40 to aid in restoring the mechanical linkages (e.g., tongue 26, pusher member 30 and associated trigger assembly 32 and advancement mechanism 34) after the fastener 6 has been ejected from the tool 2.

FIGS. 15(a) through 15(e) illustrate the various stages of an exemplary method that may be used to deliver a fastener 6 using the fastener delivery tool 2. FIG. 15(a) illustrates a cartridge 7 carrying a fastener 6 being loaded into the loading chamber 18 of the tool 2. FIG. 15(b) illustrates the cartridge retainer 16 being moved distally (in the direction of the arrow in FIG. 15(b)). This movement of the cartridge retainer 16 advances the spreader 24 (not shown in FIG. 15) to place the fastener 6 in a partially constrained state. FIG. 15(c) shows the handle 10 being depressed partially. At this stage, the teeth 26(a) of the tongue 36 drops into the loop portion of the fastener 6 and advances further distally to transform

the fastener 6 into the U-shaped configuration. Additional movement of the handle 10 transfers the fastener 6 from the loading chamber 18 to the ejection track 23 in the distal tip 4 of the tool 2.

FIG. 15(d) illustrates the compression or load-driving step whereby movement of the actuating lever 12 in the direction of the arrow A shown in FIG. 15(a) causes compression of spring 36. FIG. 15(e) illustrates the tool 2 in the fully loaded state. The fastener 6 is disposed at the distal tip 4 of the tool 2 with the tines 6(a), 6(b) projecting distally from the ejection track 23. The spring-loaded trigger 14 is then depressed to eject the fastener 6 completely from the tool 2.

FIGS. 16(a) and 16(b) illustrate alternative configurations, A, B, and C, for an elongated distal tip or snout 4 of the tool 2. The tool 2 may include distal tips 4 of varying lengths in order to facilitate the delivery process. For example, the tips 4 may have lengths between about ten and four hundred millimeters (10-400 mm), or between about five and fifty millimeters (5-50 mm).

The tips 4 may be integrally formed with the tool 2. Alternatively, the tips 4 may be removable and/or interchangeable. In this alternative, the tips 4 and/or tool 2 may include one or more detents or other connectors (not shown) for removably attaching an individual tip 4 to the tool 2. In addition, as best seen in FIG. 16(b), the elongated distal tip or snout 4 may include a variety of geometries or side-profiles, e.g., bends or curves, to increase a user's field of view and/or otherwise facilitate delivering a fastener. Thus, a tip 4 and/or tool 2 may be selected given the particular anatomical presentations encountered during a procedure.

Tip A shown in FIG. 16(b) illustrates a configuration in which the elongated distal tip 4 has a straight or flat profile. Tip B illustrates another configuration in which an

intermediate portion of the distal tip 4 is bent or curved out of the plane of the tool 2. The bent or curved configuration is particularly helpful in delivering the fastener 6 generally normal or perpendicular to the surface of the surrounding tissue 90. Tip C illustrates another configuration in which the distal tip 4 is angled with respect to the longitudinal direction of the tool 2.

Turning to FIGS. 17(a)-17(c), tool 2 may be used to deliver one or more fasteners 6, e.g., during a heart valve replacement procedure. For example, the tool 2 may be used to deliver a plurality of fasteners 6 through a sewing cuff or ring 51 of a prosthetic heart valve 50 into surrounding tissue. Alternatively, it will be appreciated that the tool 2 may be used to deliver one or more fasteners 6, e.g., to secure other devices to tissue or to another device, or to secure tissue structures together.

As shown, the prosthetic valve 50 is a multiple component prosthesis, e.g., including a gasket member 52 (around which the sewing cuff 51 may extend), and a valve member or "crown" (not shown, e.g., including a frame and a plurality of leaflets, not shown). Exemplary embodiments of single or multiple component prosthetic heart valve assemblies that may be implanted using the tool 2 are disclosed in U.S. Patent No. 6,371,983 and in co-pending applications Serial Nos. 10/327,821, filed December 20, 2002, and 10/765,725, filed January 26, 2004. The entire disclosures of these references are expressly incorporated by reference herein.

Initially, the gasket member 52 may be advanced into the annulus 90, e.g., by a separate tool (not shown), and maintained at a desired location, e.g., at a site from which native valve leaflets have been removed. The distal tip 4 of the tool 2 (loaded with a fastener 6) may be placed against the sewing cuff 51 with the tip 4 substantially perpendicular to the sewing cuff 51. The tool 2 may be actuated, e.g., by activating the

lever 12 and/or trigger 14, to deliver the fastener 6 through the sewing cuff 51 into the underlying tissue. Once the fastener 6 is ejected from the distal tip 4, the tines of the fastener 6 may at least partially recross within the tissue, thereby capturing a portion of the sewing cuff 51 and the underlying tissue within the loop of the fastener. A plurality of fasteners 6 may be successively delivered about a circumference of the sewing cuff 51 to affix the prosthetic valve 50 to the surrounding tissue 90.

FIG. 17(a) illustrates two exemplary fasteners 6 in the fully deployed state. As shown in FIG. 17(a), after penetrating the sewing cuff 51 and underlying tissue, the fasteners 6 may be biased to revert towards the parent or unconstrained state (in which the tines of the fasteners 6 at least partially overlap). In this regard, the prosthetic valve 50 may be fixedly secured to the surrounding tissue 90.

FIG 17(c) illustrates an exemplary image from a radiography device (not shown), illustrating a plurality of fasteners 6 deployed about the circumference of the prosthetic valve 50. The fasteners 6 and a portion of the gasket member 52 are at least partially radiopaque, and may be seen on a radiograph, while the sewing cuff 51 (shown in phantom in FIG. 17(c)) may be substantially radiolucent, and therefore not visible on the radiograph.

Optionally, the fasteners 6 may be removable from tissue 90 and prosthetic valve 50, e.g., if it is desired to remove the valve 50 or relocate a particular fastener. For example, a pliers-like tool (not shown) may be used to remove a fastener after ejection of the fastener 6 from the tool 2, e.g., if the fastener 6 is oriented incorrectly or the fastener 6 does not penetrate deeply enough into the tissue 90. The physician grasp the loop portion 6(c) of the fastener 6, which may remain at least partially exposed, using the pliers-like tool. The fastener 6 may then be pulled or otherwise retracted proximally to remove the

tines of the fastener 6 from the delivery site. A replacement fastener 6 may be loaded into the tool 2 and/or delivered to the delivery site, similar to the methods described above.

In an alternative embodiment, a tool may be provided that may accommodate loading multiple fasteners 6 into the tool 2 simultaneously or successively before delivery. Such a tool 2 may be desirable because the tool 2 does not have to be removed from the body cavity to load successive fasteners 6, which may accelerate delivery of the fasteners 6. FIG. 18 illustrates an embodiment of a tool 2, showing a plurality of fasteners 6 loaded into a staging area or section 42. The fasteners 6 may be advanced successively in the distal direction toward the distal tip 4 of the tool 2. A cartridge (not shown) may be provided that holds a plurality of fasteners 6 such that the tool 2 may be loaded with multiple fasteners 6 simply by loading a single cartridge into the tool 2.

While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. The invention, therefore, should not be limited, except to the following claims, and their equivalents.

We Claim:

1. A fastener delivery tool, comprising:

a loading chamber for receiving a fastener having a plurality of tines in a relaxed state;

a releasable retaining member for limiting movement of the fastener within the loading chamber;

an ejection track communicating with the loading chamber;

a handle including an actuator;

a tongue and a pusher member coupled to the actuator, activation of the actuator advancing the tongue to engage the tines so as to transform the fastener from the relaxed state to a constrained state and advancing the pusher member to advance the fastener from the loading chamber down the ejection track.

2. The fastener delivery tool of claim 1, further comprising a trigger for ejecting the fastener distally from the ejection track.

3. The fastener delivery tool of claim 1, wherein, in the relaxed state, the tines of the fastener overlap one another to define a loop, the retaining member being received in the loop for limiting movement of the fastener, and, in the constrained state, the fastener comprises a U-shape.

4. The fastener delivery tool of claim 3, wherein the ejection track comprises side walls for constraining the fastener in the U-shape as the fastener is advanced down the ejection track.

5. The fastener delivery tool of claim 4, wherein the tines are exposed distally beyond the ejection track when the actuator is activated without ejecting the fastener completely from the ejection track.

6. The fastener delivery tool of claim 1, wherein the retaining member comprises a movable release pin.

7. The fastener delivery tool of claim 6, wherein the release pin is coupled to at least one of the tongue and the pusher member such that the release pin releases the fastener after the actuator is activated.

8. The fastener delivery tool of claim 1, further comprising a staging section including a plurality of fasteners disposed therein.

9. The fastener delivery tool of claim 8, wherein the plurality of fasteners are carried by a cartridge receivable in the staging section.

10. The fastener delivery tool of claim 1, the retaining member being releasable upon engagement with a cam located on the pusher member.

11. The fastener delivery tool of claim 1, wherein the fastener includes two tines that overlap one another in the relaxed state.

12. A fastener delivery tool, comprising:

a loading chamber for receiving at least one fastener having a pair of tines overlapping one another in a relaxed state, the loading chamber including a release pin on which said at least one fastener is loaded;

an ejection track communicating with the loading chamber; and

an actuator coupled to a tongue and a pusher member, activation of the actuator causing the tongue to engage the plurality of tines to transform the fastener from the relaxed state to a constrained state and causing the pusher member to advance the fastener in the constrained state from the loading chamber down the ejection track.

13. The fastener delivery tool of claim 12, wherein the at least one fastener has a U-shape in the constrained state.

14. The fastener delivery tool of claim 12, further comprising a trigger for ejecting the at least one fastener from the ejection track.

15. A method for delivering a fastener, comprising:

restraining a fastener within a delivery tool using a retaining member, the fastener comprising a pair of tines;

advancing a tongue in the delivery tool relative to the restrained fastener to transform the fastener from a relaxed state to a constrained state;

releasing the fastener from the retaining member while the fastener is in the constrained state;

advancing the fastener in the constrained state distally within the delivery tool; and

ejecting the fastener from the delivery tool.

16. The method of claim 15, wherein the delivery tool carries a plurality of fasteners therein.

17. The method of claim 16, further comprising loading a cartridge into the delivery tool, the cartridge carrying the plurality of fasteners.

18. The method of claim 15, wherein the tongue and fastener are advanced successively upon activating an actuator.

19. The method of claim 15, wherein the constrained state comprises a U-shaped fastener.

20. The method of claim 15, further comprising depressing a trigger on the delivery tool to eject the fastener completely from the delivery tool.

21. The method of claim 15, wherein the fastener is advanced distally within the delivery tool in the constrained state by depressing a lever on the delivery tool.

22. A method for securing a heart valve prosthesis within a tissue annulus, comprising:

restraining a fastener within a delivery tool using a retaining member;

advancing a tongue in the delivery tool relative to the restrained fastener to transform the fastener from a relaxed state to a constrained state;

releasing the fastener from the retaining member while the fastener is in the constrained state;

advancing the fastener in the constrained state distally within the delivery tool; and

ejecting the fastener from the delivery tool through a component of a heart valve prosthesis into the tissue annulus.

23. The method of claim 22, wherein the fastener includes a pair of tines that overlap in the relaxed state to define a loop, the retaining member being received in the loop to restrain the fastener.

24. The method of claim 23, wherein the tongue is received in the loop such that, as the tongue is advanced, the tongue moves the tines into a U-shape in the constrained state.

25. The method of claim 22, wherein the fastener resiliently moves towards the relaxed state after the fastener is ejected from the from the delivery tool to capture tissue between the tines.

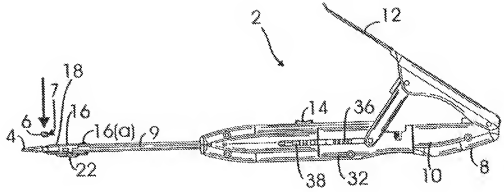


FIG. 1

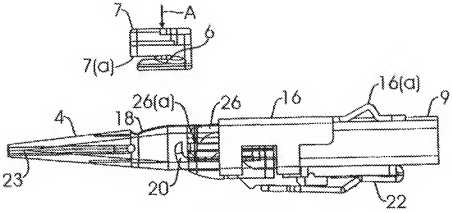


FIG. 2(a)

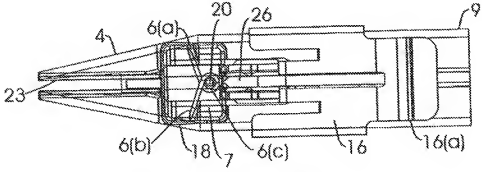


FIG. 2(b)

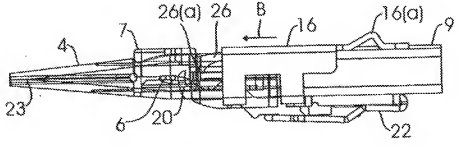


FIG. 3(a)

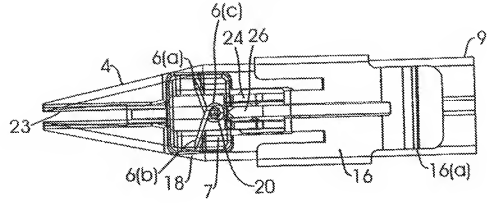


FIG. 3(b)

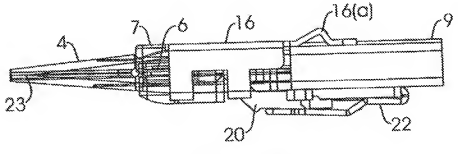


FIG. 4(a)

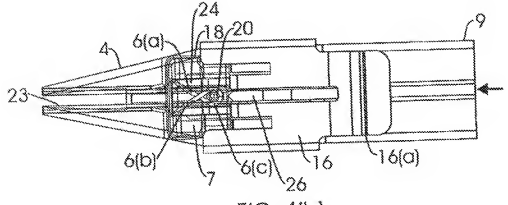


FIG. 4(b)

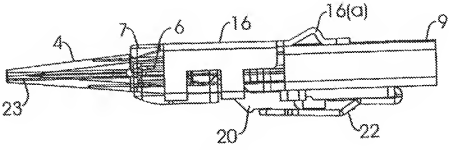


FIG. 5(a)

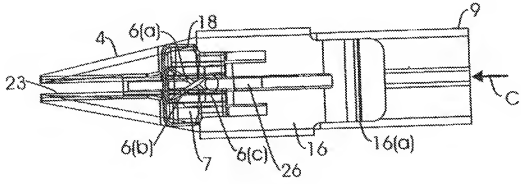


FIG. 5(b)

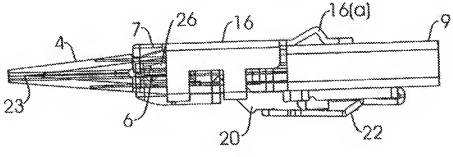


FIG. 6(a)

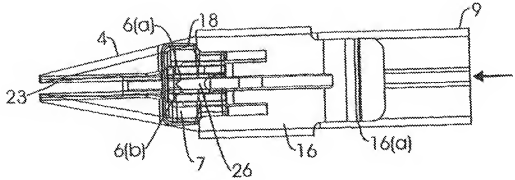


FIG. 6(b)

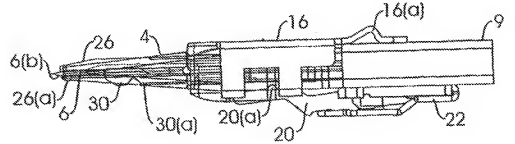


FIG. 7(a)

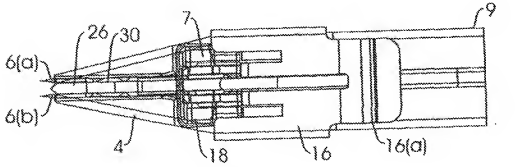
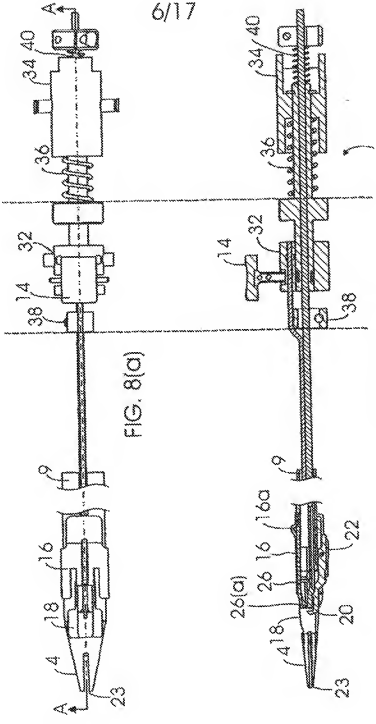


FIG. 7(b)


A
40
34
36
32
14
38
9
16
18
4
23
A
FIG. 8(a)
40
34
36
2
32
14
38
9
16a
22
16
26
26(a)
20
18
4
23
FIG. 8(b)
Section A-A

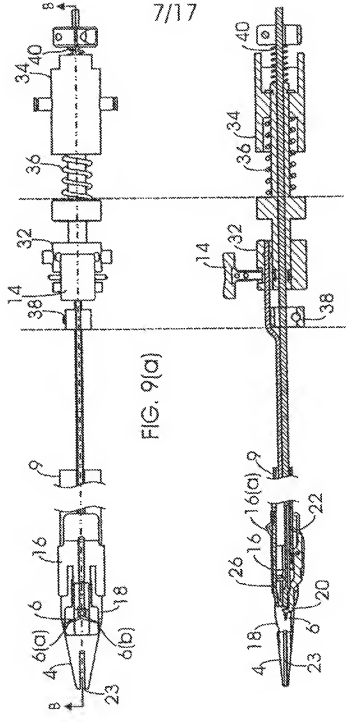
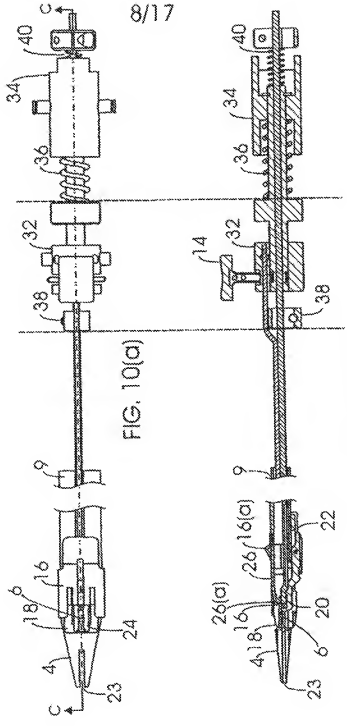
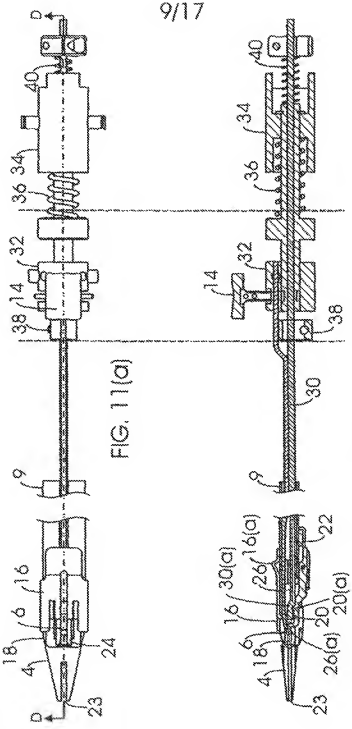


FIG. 9(a)

FIG. 9(b)
Section B-B


C
40
34
36
32
38
9
16
6
18
24
4
23
C
FIG. 10(a)
40
34
36
14
32
38
9
16(a)
22
26
26(a)
16
20
18
6
4
23
FIG. 10(b)
Section C-C


D
40
34
36
32
14
38
9
16
6
18
4
24
23
D
FIG. 11(a)
40
34
36
32
14
38
30
9
22
16(a)
30(a)
26
16
20
20(a)
6
18
4
26(a)
23
FIG. 11(b)
Section D-D

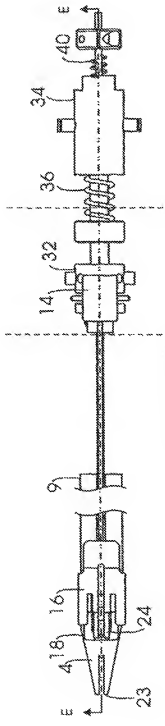


FIG. 12(a)

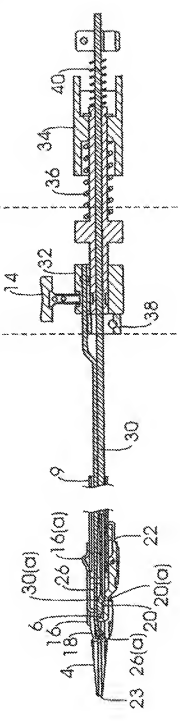


FIG. 12(b)
Section E-E

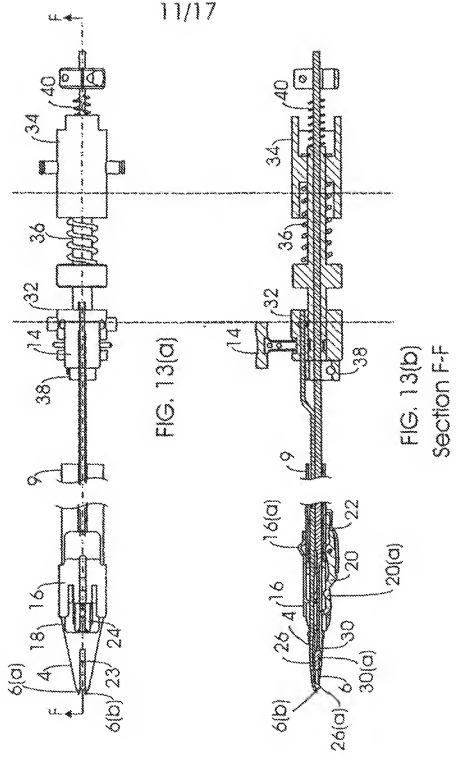


FIG. 13(a)

FIG. 13(b)
Section F-F

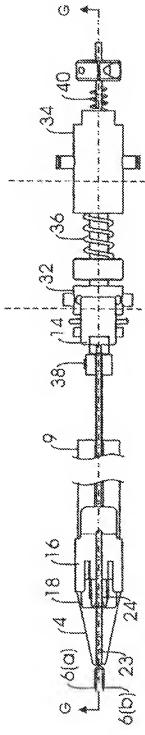


FIG. 14(a)

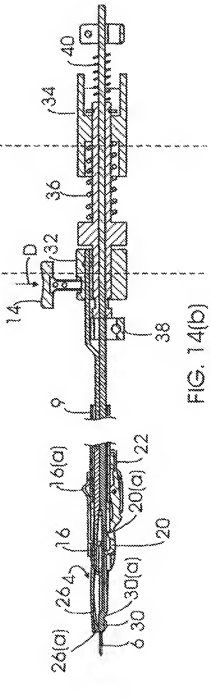


FIG. 14(b)
Section G-G

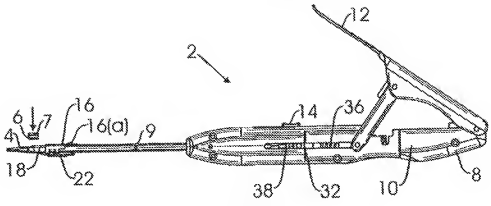


FIG. 15(a)

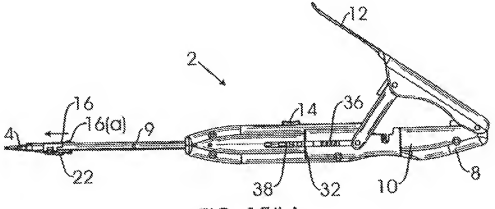


FIG. 15(b)

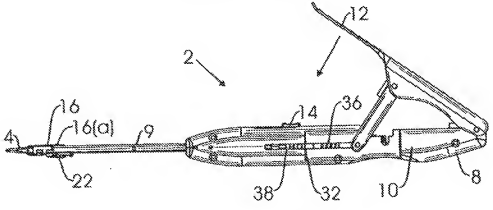


Fig. 15(c)

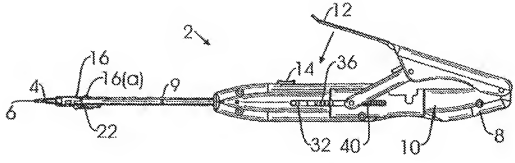


FIG. 15(d)

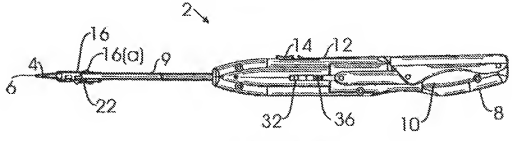


FIG. 15(e)

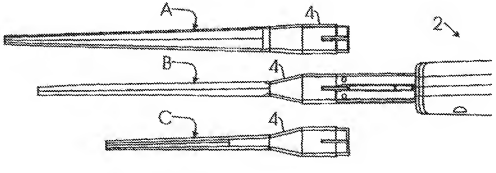


FIG. 16(a)

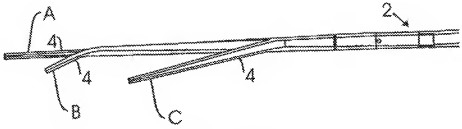


FIG. 16(b)

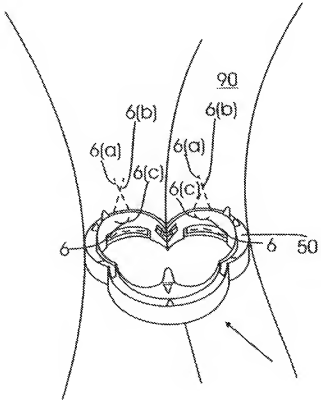


FIG. 17(a)

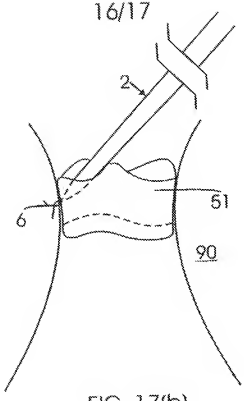


FIG. 17(b)

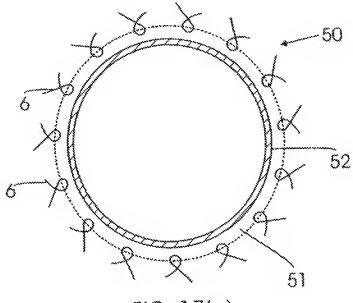


FIG. 17(c)

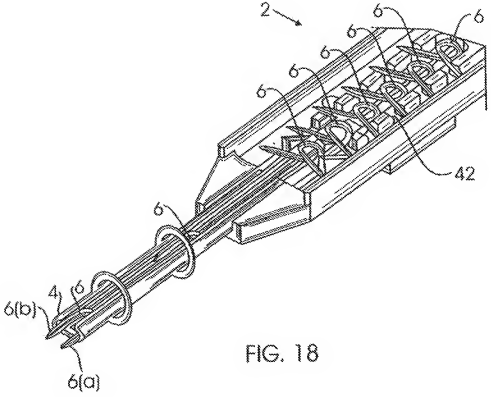


FIG. 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/043503

A. CLASSIFICATION OF SUBJECT MATTER
A61B17/068 A61B17/064

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 618 311 A (GRYSKIEWICZ ET AL) 8 April 1997 (1997-04-08) column 3, line 53 - column 4, line 18 column 4, line 46 - column 67, line 24 figures	1-3, 11-14
A	US 2004/093024 A1 (LOUSARARIAN JAMES [US] ET AL) 13 May 2004 (2004-05-13) column 8, line 7 - column 9, line 54 figures	1,2,12, 14
A	US 5 304 204 A (BREGEN ET AL) 19 April 1994 (1994-04-19) column 6, line 37 - column 7, line 47 figures 11-18	1,12,13

-/---

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 March 2006	29/03/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Nistor, L

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/043503

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 993 465 A (SHIPP ET AL) 30 November 1999 (1999-11-30) paragraph [0034] - paragraph [0040] paragraph [0092] - paragraph [0095] figures 12-17,67-71	1,2, 12-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/043503

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-25
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

ormation on patent family members

International application No
PCT/US2005/043503

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5618311	A	08-04-1997	NONE		
US 2004093024	A1	13-05-2004	NONE		
US 5304204	A	19-04-1994	AT	147248 T	15-01-1997
			AU	668452 B2	02-05-1996
			AU	5503794 A	11-08-1994
			CA	2115131 A1	10-08-1994
			DE	69401364 D1	20-02-1997
			DE	69401364 T2	28-05-1997
			ES	2096408 T3	01-03-1997
			GR	94100053 A	31-10-1994
			JP	7000404 A	06-01-1995
US 5993465	A	30-11-1999	NONE		